DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
g 1543d

60 8th Street, N.E.
Atlanta, Georgia 30309

July 16, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph R. Daniels, President
Wanchese Fish Company, Inc.
Mill Landing Road, P.O. Box 369
Wanchese, NC 27981

Warning Letter
01-ATL-64

Dear Mr. Daniels:

On May 21-22, 2001, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your plant located at Mill Landing Road, Wanchese, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh histamine-producing fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your HACCP plan for histamine- producing fish does not list the critical control point of finished product storage for controlling the food safety hazard of histamine formation. This deviation was previously brought to your attention in our letter of October 30, 1998.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan does not list a critical limit for adequacy of ice even though it calls for a visual observation of the adequacy of ice on incoming histamine-producing fish.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, during the period of March 1, 2001 through May 19, 2001 there were many instances where monitoring observations required at the "Receiving Histamine Fish" critical control point were missing from the records.

Specifically, many of your monitoring records for this period failed to include: the internal temperature measurements taken by your employee(s); signed statements from the fishermen; written observations about the adequacy of ice; and/or results of the sensory examinations conducted to determine decomposition in incoming fish. In fact, you had no documentation that the checks for adequacy of ice or sensory examinations for decomposition have ever been conducted.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District